

Electronics, Inc. from Arlington, Virginia to McLean, Virginia; and Rockwell International Corporation from El Segundo, California to Seal Beach, California.

A copy of the amended certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

Dated: July 11, 1995.

W. Dawn Busby,

Director, Office of Export Trading Company Affairs.

[FR Doc. 95-17353 Filed 7-13-95; 8:45 am]

BILLING CODE 3510-DR-P

National Institute of Standards and Technology

Judges Panel of the Malcolm Baldrige National Quality Award

AGENCY: National Institute of Standards and Technology Department of Commerce.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2, notice is hereby given that there will be a closed meeting of the Judges Panel of the Malcolm Baldrige National Quality Award on Wednesday, August 9, 1995. The Judges Panel is composed of nine members prominent in the field of quality management and appointed by the Secretary of Commerce. The purpose of this meeting is to review the 1995 Award applications and to select applications to be considered in the site visit stage of the evaluation. The applications under review contain trade secrets and proprietary commercial information submitted to the Government in confidence.

DATES: The meeting will convene August 9, 1995, at 8 a.m. and adjourn at 5 p.m. on August 9, 1995. The entire meeting will be closed.

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, Administration Building, Gaithersburg, Maryland 20899.

FOR FURTHER INFORMATION CONTACT: Dr. Curt W. Reimann, Director for Quality Programs, National Institute of Standards and Technology, Gaithersburg, Maryland 20899, telephone number (301) 975-2036.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on March 3, 1994, that the meeting of the Panel of

Judges will be closed pursuant to Section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. app. 2, as amended by Section 5(c) of the Government in the Sunshine Act, P.L. 94-409. The meeting, which involves examination of records and discussion of Award applicant data, may be closed to the public in accordance with Section 552b(c)(4) of Title 5, United States Code, since the meeting is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential.

Dated: July 7, 1995.

Samuel Kramer,

Associate Director.

[FR Doc. 95-17316 Filed 7-13-95; 8:45 am]

BILLING CODE 3510-13-M

Patent and Trademark Office

[Docket No. 950706172-5172-01]

Utility Examination Guidelines

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The Patent and Trademark Office (PTO) is publishing the final version of guidelines to be used by Office personnel in their review of patent applications for compliance with the utility requirement. Because these guidelines govern internal practices, they are exempt from notice and comment and delayed effective date rulemaking requirements under 5 U.S.C. 553(b)(A).

EFFECTIVE DATE: July 14, 1995.

FOR FURTHER INFORMATION CONTACT: Jeff Kushan by telephone at (703) 305-9300, by fax at (703) 305-8885, by electronic mail at kushan@uspto.gov, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231.

SUPPLEMENTARY INFORMATION:

I. Discussion of Public Comments

Forty-four comments were received by the Office in response to the request to public comment on the proposed version of utility guidelines published on January 3, 1995 (60 FR 97). All comments have been carefully considered. A number of changes have been made to the examining guidelines and the legal analysis supporting the guidelines in response to the comments received.

Many of the individuals responding to the request for public comments suggested that the Office address the relationship between the requirements

of 35 U.S.C. 112, first paragraph, and 35 U.S.C. 101. The Office has amended the guidelines to provide a clarification consistent with these requests. The guidelines now specify that any rejection based on a "lack of utility" under section 101 should be accompanied by a rejection based upon section 112, first paragraph. The guidelines also specify that the procedures for imposition and review of rejections based on lack of utility under section 101 shall be followed with respect to the section 112 rejection that accompanies the section 101 rejection.

A suggestion was made that the guidelines should be modified to provide that an application shall be presumed to be compliant with section 112, first paragraph, if there is no proper basis for imposing a section 101 rejection. This suggestion has not been followed. Instead, the guidelines specify that section 112, first paragraph, deficiencies other than those that are based on a lack of utility be addressed separately from those based on a lack of utility for the invention.

Several individuals suggested that the guidelines address how section 101 compliance will be reviewed for products that are either intermediates or whose ultimate function or use is unknown. The Office has amended the guidelines to clarify how it will interpret the "specific utility" requirement of section 101.

Some individuals suggested that the guidelines be amended to preclude Examiners from requiring that an applicant delete references made in the specification to the utility of an invention which are not necessary to support an asserted utility of the claimed invention. The guidelines have been amended consistent with this suggestion.

One individual suggested that the legal analysis be amended to emphasize that any combination of evidence from *in vitro* or *in vivo* testing can be sufficient to establish the credibility of an asserted utility. The legal analysis has been amended consistent with this recommendation.

A number of individuals questioned the legal status of the guidelines, particularly with respect to situations where an applicant believes that a particular Examiner has failed to follow the requirements of the guidelines in imposing a rejection under section 101. The guidelines and the legal analysis supporting the guidelines govern the internal operations of the Patent and Trademark Office. They are not intended to, nor do they have the force and effect of law. As such they are not substantive rules creating or altering the

rights or obligations of any party. Rather, the guidelines define the procedures to be followed by Office personnel in their review of applications for section 101 compliance. The legal analysis supporting the guidelines articulates the basis for the procedures established in the guidelines. Thus, an applicant who believes his or her application has been rejected in a manner that is inconsistent with the guidelines should respond substantively to the grounds of the rejection. "Non-compliance" with the guidelines will not be a petitionable or appealable action.

Some individuals suggested that the guidelines and legal analysis be amended to specify that the Office will reject an application for lacking utility only in those situations where the asserted utility is "incredible." This suggestion has not been adopted. The Office has carefully reviewed the legal precedent governing application of the utility requirement. Based on that review, the Office has chosen to focus the review for compliance with Section 101 and Section 112, first paragraph, on the "credibility" of an asserted utility.

Some individuals suggested that the guidelines be amended to address how a generic claim that covers many discrete species will be assessed with regard to the "useful invention" requirements of sections 101 and 112 when one or more, but not all, species within the genus do not have a credible utility. The guidelines have been amended to clarify how the Office will address applications in which genus claims are presented that encompass species for which an asserted utility is not credible. The legal analysis makes clear that any rejection of any claimed subject matter based on lack of utility must adhere to the standards imposed by these guidelines. This is true regardless of whether the claim defines only a single embodiment of the invention, multiple discrete embodiments of the invention, or a genus encompassing many embodiments of the invention. As cast in the legal analysis and the guidelines, the focus of examination is the invention as it has been defined in the claims.

Some individuals questioned whether the guidelines and the legal analysis govern actions taken by Examining Groups other than Group 1800 or the Board of Patent Appeals and Interferences. The guidelines apply to all Office personnel, and to the review of all applications, regardless of field of technology.

In addition to the changes made in response to comments from the public,

the Office has amended the guidelines to clarify the procedure to be followed when an applicant has failed to identify a specific utility or an invention. The guidelines now provide that where an applicant has made no assertion as to why an invention is believed useful, and it is not immediately apparent why the invention would be considered useful, the Office will reject the application as failing to identify any specific utility for the invention. The legal analysis has also been amended to address evaluation of this question.

II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. Introduction

The following guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any application for compliance with the utility requirements of 35 U.S.C. 101 and 112. The guidelines also address issues that may arise during examination of applications claiming protection for inventions in the field of biotechnology and human therapy. The guidelines are accompanied by an overview of applicable legal precedent governing the utility requirement. The guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The guidelines and the legal analysis do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate review of applications for compliance with this statutory requirement.

B. Examination Guidelines for the Utility Requirement

Office personnel shall adhere to the following procedures when reviewing applications for compliance with the "useful invention" ("utility") requirement of 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph.

1. Read the specification, including the claims, to:

(a) Determine what the applicant has invented, noting any specific embodiments of the invention;

(b) Ensure that the claims define statutory subject matter (e.g., a process, machine, manufacture, or composition of matter);

(c) Note if applicant has disclosed any specific reasons why the invention is believed to be "useful."

2. Review the specification and claims to determine if the applicant has asserted any credible utility for the claimed invention:

(a) If the applicant has asserted that the claimed invention is useful for any

particular purpose (i.e., a "specific utility") and that assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. Credibility is to be assessed from the perspective of one of ordinary skill in the art in view of any evidence of record (e.g., data, statements, opinions, references, etc.) that is relevant to the applicant's assertions. An applicant must provide only one credible assertion of specific utility for any claimed invention to satisfy the utility requirement.

(b) If the invention has a well-established utility, regardless of any assertion made by the applicant, do not impose a rejection based on lack of utility. An invention has a well-established utility if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties of a product or obvious application of a process).

(c) If the applicant has not asserted any specific utility for the claimed invention and it does not have a well-established utility, impose a rejection under section 101, emphasizing that the applicant has not disclosed a specific utility for the invention. Also impose a separate rejection under section 112, first paragraph, on the basis that the applicant has not shown how to use the invention due to lack of disclosure of a specific utility. The sections 101 and 112, rejections should shift the burden to the applicant to:

- Explicitly identify a specific utility for the claimed invention, and
- Indicate where support for the asserted utility can be found in the specification.

Review the subsequently asserted utility by the applicant using the standard outlined in paragraph (2)(a) above, and ensure that it is fully supported by the original disclosure.

3. *If no assertion of specific utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a well-established utility, reject the claim(s) under section 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under section 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed.* The section 112, first paragraph, rejection imposed in conjunction with a section 101 rejection should incorporate by reference the grounds of the corresponding section 101 rejection and should be set out as a rejection distinct from any other

rejection under section 112, first paragraph, not based on lack of utility for the claimed invention.

To be considered appropriate by the Office, any rejection based on lack of utility must include the following elements:

(a) *A prima facie showing that the claimed invention has no utility.*

A *prima facie* showing of no utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific utility asserted by the applicant for the claimed invention. A *prima facie* showing must contain the following elements:

(i) A well-reasoned statement that clearly sets forth the reasoning used in concluding that the asserted utility is not credible;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) Support for any conclusions regarding evidence provided by the applicant in support of an asserted utility.

(b) *Specific evidence that supports any fact-based assertions needed to establish the prima facie showing.*

Whenever possible, Office personnel must provide documentary evidence (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) as the form of support used in establishing the factual basis of a *prima facie* showing of no utility according to items (a)(ii) and (a)(iii) above. If documentary evidence is not available, Office personnel shall note this fact and specifically explain the scientific basis for the factual conclusions relied on in sections (a)(ii) and (a)(iii).

4. *A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art in view of all evidence of record.*

Once a *prima facie* showing of no utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a printed publication, that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, Office personnel shall review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments and any new reasoning or evidence provided by the applicant in support of an asserted utility. It is essential for Office personnel to recognize, fully

consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under section 101, withdraw the section 101 rejection and the corresponding rejection imposed under section 112, first paragraph, per paragraph (3) above.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

III. Additional Information

The PTO has prepared an analysis of the law governing the utility requirement to support the guidelines outlined above. Copies of the legal analysis can be obtained from Jeff Kushan, who can be reached using the information indicated above.

Dated: July 3, 1995.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 95-17304 Filed 7-13-95; 8:45 am]

BILLING CODE 3510-16-M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: August 14, 1995.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403,

1735 Jefferson Davis Highway, Arlington, Virginia 22202-3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603-7740.

SUPPLEMENTARY INFORMATION: On July 22, 1994, April 28, May 12 and 19, 1995, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (59 FR 37466, 60 FR 20971, 25695 and 26876) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services, fair market price, and impact of the additions on the current or most recent contractors, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the services proposed for addition to the Procurement List.

Accordingly, the following services are hereby added to the Procurement List:

Administrative Services for the following locations:

Fleet and Industrial Supply Center, San Diego, California

Fleet and Industrial Supply Center, Long Beach, California

Janitorial/Custodial for the following locations:

Federal Building, 525 Water Street, Port Huron, MI

Social Security Administration Building, 142 Auburn Street, Pontiac, MI

Janitorial/Custodial, Carl Albert Federal Building and U.S. Courthouse, 301 E. Carl Albert Parkway, McAlester, Oklahoma

Janitorial/Custodial, IRS Service Center Complex, Memphis, Tennessee